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EXAMINER

THOMPSON, MICHAEL M

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 12/03/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,400

Applicant(s)

DING ET AL. *cn*

Examiner

Michael M. Thompson

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-- Th MAILING DATE of this communication appears on th cov r sheet with th corr spondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or PTO-1449, they have not been considered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the perfusion lumen of claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: The specification is replete with added subject matter in the margins of the submitted disclosure. Applicant is requested to file a corrected specification with the specified additions for clarity of examination.

Appropriate correction is required.

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4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The means for infusing lacks proper antecedent basis in the specification. It is assumed that Applicant is referring to the infusion means of claim 17.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 14, 17-23, 25, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Just et al. (5,232,444) in view of Sahatjian (5,304,121). Just et al teaches all of the limitations of the claims except for explicitly reciting a non-hydrogel polymer having a plurality of voids. Sahatjian teaches the use of a non-hydrogel polymer having a plurality of voids. It would have been obvious to one of ordinary skill in the art, at the time of invention to

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have modified the sponge coating of Just et al. with the non-hydrogel polymer sponge coating of Sahatjian for the well known purpose of releasing drug solutions to a patient due to the compressibility of sponge-like polymers in response to pressure.

8. Claims 15-16, 24, 26, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Just et al. (5,232,444) in view of Sahatjian (5,304,121) as applied to claims 14, 17-23, 25, and 27-33 above, and further in view of Helmus et al. (5,447,724). Just et al. and Sahatjian teach all of the limitations of the claims except for explicitly reciting voids with space of the coating greater than about 60% of the volume of the coating wherein the particulate material is eluted *in vivo* with or without a solvent. Helmus et al. teaches a coating or reservoir that contains a particulate material or agent comprising more than about 30% by weight of the agent to the reservoir, preferably about 40% to 60% by weight of the agent which is eluted *in vivo*.

Therefore, Helmus et al. is specifically teaching voids large enough to carry within the reservoir comprised "voids" capable of containing particulate or agent in the percentages supra. It is well known that "voids" or "pore" in the reservoir of coatings are commonly constructed via elution or extraction of particulate matter and the porosity is determined by the size of the elutable particles ...and by the concentration of those particles as a percent by volume of a pre-elution mixture thereof with the polymer. This is consistent with the teachings of Helmus et al. with respect to coatings. It is submitted, therefore, that it would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the sponge coating of Sahatjian with the characteristics supra of Helmus et al. for the well known purpose of a prolonged release at effective levels for several hours and/or for the purpose of releasing a greater quantity of agent to the patient.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 14-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,364,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the above-mentioned claims recite substantially similar inventions such as a catheter for delivering a biologically active material comprising a reservoir having a plurality of pore therein and a non-hydrogel polymer sponge coating having a plurality of voids wherein the void space of the sponge coating is greater than about 60% of the volume of the sponge coating, the polymer comprising an elastomer, a means for infusing, eluting a particulate material from the polymer and heparin as the biologically active material.

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Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619.

The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

MT



November 30, 2003



BRIAN L. CASLER
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